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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,879	08/05/2002	Nnochiri N. Ekwuribe	9233-74	8724

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EXAMINER

RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 04/21/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/018,879

Applicant(s)

EKWURIBE ET AL.

Examiner

Jeffrey E. Russel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 August 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8,9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the city and either state or foreign country of residence of each inventor. The residence information may be provided on either on an application data sheet or supplemental oath or declaration.

The city of residence of inventors Ramaswamy and Rajagopalan is omitted from the declaration filed August 5, 2002.

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

After an acceptable claim for priority has been submitted, the examiner will forward the request for corrected filing receipt filed December 17, 2002 for action.

3. The disclosure is objected to because of the following informalities: There is no Brief Description of the Drawings as required by 37 CFR 1.74. At page 8, line 3, "amphiphilicity" is misspelled. At page 22, line 11, "patient" is misspelled. The status of the U.S. patent application cited at page 40, line 29, should be updated. Appropriate correction is required.

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4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 50-69 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15-20 and 56-60 of U.S. Patent No.

6,309,633. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '633 patent anticipate the instant claims.

7. Claims 50-63 and 65-68 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-67 of copending Application No. 09/873,899. Although the conflicting claims are not identical, they are not patentably distinct from each other. The '899 application claims insulin conjugated to a first polyethylene glycol moiety, which is conjugated through a hydrolyzable bond to a second polyethylene glycol moiety, which is conjugated to a lipophilic moiety. The polyethylene glycol moieties can have at least 2 polyethylene glycol subunits. The lipophilic moieties can be alkyl or fatty acid moieties. The conjugates are amphiphilically balanced so that each conjugate is aqueously soluble and able to penetrate biological membranes. The '899 application does not claim Applicants' specific H, H', and fatty acid moiety sizes. It would have been obvious to one of ordinary skill in the art to determine all operable and optimal H, H', and fatty acid moiety

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sizes for the claimed conjugates of the '899 application because the '899 application recites in its claims that PEG size is to be determined, because polymer size is an art-recognized result-effective variable which is routinely determined and optimized in the polymer and conjugate arts, and because it is necessary to determine and optimize H, H', and fatty acid moiety sizes in the claimed conjugates of the '899 application in order to amphiphilically balance the conjugates as is required in claim 28 of the '899 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

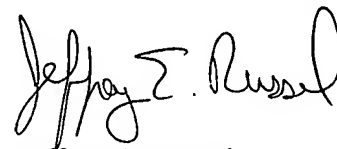
8. Ekwuribe (U.S. Patent No. 5,359,030, see especially column 13, Conjugates 1 and 2) is deemed to be the closest prior art of record; however, this reference, either alone or in combination with the other prior art of record, is not deemed to teach or suggest Applicants' claimed drug-oligomer conjugates in which a PEG polymer H is conjugated to a hydrophilic moiety H' through a hydrolyzable bond. Note that the Zalipsky et al article (Reference 70 of the Information Disclosure Statement filed September 9, 2002), page 349, first full paragraph, teaches that ether bonds are non-hydrolyzable, and accordingly none of the ether bonds present in Conjugates 1 and 2 of Ekwuribe satisfy Applicants' claimed requirements for a hydrolyzable H-H' bond. Regen (U.S. Patent No. 5,606,038) also does not teach or suggest the presence of a hydrolyzable H-H' bond in its conjugates, and does not teach or suggest conjugates comprising insulin.

9. Reference 99, crossed off of the Information Disclosure Statement filed February 3, 2003, was not considered because it is not in the English language and no concise explanation of its relevance was provided as required by 37 CFR 1.98(a)(3)(i).

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel

Primary Patent Examiner

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JRussel

April 19, 2003